

K213770 SP-CL Hip Stem and LCU Hip SystemSep 13, 2022
285 days to decisionK213770 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k213770/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	Dec 2, 2021
Decision date	Sep 13, 2022
Days to decision	285 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Waldemar Link GmbH & Co. KG
Location	Mchenry, IL, US
Contact	Pia Müller
510(k) history	42 submissions · 42 cleared · 1978-2025

REGULATORY CONSULTANT

Consulting firm	LinkBio Corp.
Contact	Pia Müller

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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